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January 29, 1999

Dr. C.W. Jameson
NTP Report on Carcinogens
79 Alexander Drive, Room 3217
P.O. Box 12233
Research Triangle Park, NC 27709

Dear Dr. Jameson:

As the Senior Attorney for the Tobacco Control Resource Center (TCRC), which is based at Northeastern University School of Law in Boston, I am submitting comments on behalf of TCRC regarding the proposed listing of environmental tobacco smoke (ETS) as a "known" cause of human cancer in the federal government's Ninth Report on Carcinogens.

Principally, I wish to convey to you and your colleagues some of our knowledge of the long and shameful history of the tobacco industry's disinformation campaign about the hazards of ETS. Internal industry memos were cited in an April 1998 *Wall Street Journal* article that began: "Determined to keep reports about secondhand smoke from mushrooming, the tobacco industry mobilized a counterattack in the mid-1980s to systematically discredit any researcher claiming perils from passive smoke."

In a February 25, 1985 letter, Anthony Colucci, who was a top scientist at R/J/ Reynolds Tobacco Co., wrote to H.E. Osmon, a director of public affairs at Reynolds: "We anticipate that if (then-EPA scientist James) Repace runs true to form there will be a good deal of media copy written about their (Repace's and naval researcher Alfred Lowrey's) analyses and thus we should begin eroding confidence in this work as soon as possible." Compare this with the pledge the tobacco industry made to the public in full-page ads taken out in newspapers across America in January 1954: "We do not believe that any serious medical research, even though its results are inconclusive, should be disregarded or lightly dismissed.... **We accept an interest in people's health as a basic responsibility paramount to every other consideration in our business."** (emphasis added)

Even before Colucci's letter, the tobacco industry had long sought to discredit those who report on the hazards of ETS. In a 1981 Philip Morris document, an executive suggests funding studies "with the intent to publish data which refutes specific assertions by the anti-smoking forces." An official for BAT Industries (the parent company of Brown & Williamson Tobacco Co. in the United States) in 1993 listed as a strategy: "Conduct research to anticipate and refute claims about the health effects of passive smoking."

Furthermore, a study published in May 1998 in the *Journal of the American Medical Association* showed that of the articles that examined the health effects of breathing ETS, 37 percent (39 out of 106) concluded that exposure to ETS is not harmful to health. Of those 39 articles, 29 – or 74 percent – were written by authors with tobacco industry affiliations.

In August 1998, the St. Paul Pioneer Press reported that the tobacco industry has paid 13 scientists a total of $156,000 to write letters to influential publications criticizing the 1993 EPA report on the hazards of secondhand smoke. In fact, a member of the editorial board of the *Journal of Regulatory Toxicology and Pharmacology*, along with a colleague, was paid $25,000 to write an article for his own publication. This pollution of the scientific literature had the desired effect of misleading the public by exaggerating the extent of genuine scientific controversy over the health effects of ETS. As Julia Carol, co-director of Americans for Non-smokers' Rights, put it, referring to the 13 who accepted tobacco money for this purpose: "They're not scientists, they're prostitutes."

Much of the tobacco industry's disinformation about the health effects of ETS has come in the context of the political lawsuit it filed in 1993 against the EPA shortly after the release of its landmark report, *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders* (EPA/600/6-901/006 F). The industry's lawsuit was the central feature of a high-profile advertising, public relations and litigation campaign to cast doubt on the report's conclusions. In July 1998, U.S. District Judge William Osteen issued a ruling that purports to "vacate" major portions of the EPA report. *Flue-Cured Tobacco Cooperative Stabilization Corp. v. Environmental Protection Agency*, 4 F.Supp. 435 (M.D.N.C. 1998). In his opinion, Osteen – a non-scientist – adopts the tobacco industry's version of what is good science, overruling the unanimous conclusions of an independent panel of experts.

I am attaching to my comments a detailed analysis of Judge Osteen's ruling. The analysis, prepared by my colleague and TCRC Managing Attorney Graham Kelder, explains why Judge Osteen's ruling is fundamentally flawed and will likely be overturned on appeal. It should be emphasized that, less than three weeks after Judge Osteen's ruling, U.S. District Judge Jacob Mishler denied a request by restaurant owners for a preliminary injunction against a law that prohibits smoking in the bar areas of restaurants in Suffolk County, New York. "It is beyond dispute that secondhand smoke is a carcinogen," Mishler ruled. *Sayville Inn 1888 Corp. v. County of Suffolk*, No. 98-CV-4527 (E.D.N.Y., August 3, 1998).

Sincerely,

Edward L. Sweda, Jr.

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Tobacco Control Resource Center

# MISTAKEN RULING, UNMISTAKABLE FACTS:

## How Judge Osteen Got It Wrong When He Vacated The EPA's Finding That Secondhand Smoke Is A Known Carcinogen and Why His Ruling May Not Matter

Big tobacco is breathing a little easier these days, but big tobacco is hoping that the rest of us may soon not be. On July 17, 1998, after five years of court proceedings, Judge William L. Osteen of the United States District Court for the Middle District of North Carolina granted the tobacco industry plaintiffs' motion for partial summary judgment in *Flue-Cured Tobacco Cooperative Stabilization Corporation v. EPA*.[1] In so ruling, Judge Osteen vacated chapters one through six and the appendices to the EPA's landmark 1992 report titled *Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders*.[2] Chapter One included the EPA's classification of secondhand smoke as a Known Human (Group A) Carcinogen.

Tobacco Control advocates and plaintiffs attorneys need to keep in mind that 1) the EPA's risk assessment for respiratory illnesses in children remains intact; 2) Judge Osteen vacated the EPA's classification of secondhand smoke as a Known Human (Group A) Carcinogen for reasons that are now the subject of heated debate and will, in all likelihood, form the basis for the EPA's appeal of Osteen's decision; 3) many analysts believe that Osteen, a former lobbyist for tobacco farmers, should have recused himself from the case; 4) many analysts also contend that Osteen may have overstepped his bounds in substituting his scientific judgment for that of the EPA; 5) many commentators assert that the science behind the EPA's report is solid (in stark contrast to the obviously-biased research on secondhand smoke funded by the tobacco industry); 6) scores of other studies confirm the EPA's findings; 7) Osteen's ruling does not affect the validity of state and local clean indoor air laws; and 8) in another case a federal judge in New York recently declared that, "[I]t is beyond dispute that second-hand smoke is a carcinogen."

### What Judge Osteen Actually Decided and Why

In his July 17th ruling, Judge Osteen vacated the EPA's classification of secondhand smoke as a Known Human (Group A) Carcinogen. He did not, however, invalidate the EPA's extensive findings regarding secondhand smoke and respiratory disorders other than lung cancer. The EPA's findings, thus, remain intact regarding secondhand smoke and its effects on

Congress," because the EPA had failed to establish and consult with the second advisory group required by the Act, i.e., the one "comprised of individuals representing the States, the scientific community, industry, and public interest organizations...."[10] Judge Osteen found unpersuasive the EPA's arguments that it had consulted with the functional equivalent of this second advisory by establishing and consulting with a subcommittee of its advisory board - the Indoor Air Quality/Total Human Exposure Committee ("IAQC") - that included what the EPA asserted were a former tobacco industry scientist and panelists who had received tobacco industry funding:

> The IAQC group that provided advice to the EPA on the ETS Risk Assessment was not the representative body required by § 7403(c).... EPA's argument that IAQC was a representative body is without merit. IAQC's membership did not include individuals from industry or representatives from more than one state. No members were invited to represent or admitted to representing any constituency. Rather, EPA's regulations prohibited parties with meaningful outside interests from participating [in SAB activities]. Accordingly, EPA failed to comply with the requirements of § 7403(c).[11]

Judge Osteen then went on to declare that the ETS risk assessment constituted "an agency characterization promulgated without adherence to statutory procedure," and found that the court had to vacate the EPA's ETS risk assessment in order to satisfy the Radon Research Act's procedural requirements.[12]

Judge Osteen next found fault with the scientific methodology used by the EPA in conducting its risk assessment. Osteen specifically concluded that

· Plaintiffs "rais[ed] legitimate questions not addressed in the record regarding EPA's bioplausibility theory," leaving "[t]he court...faced with the ugly possibility that EPA adopted a methodology for each chapter, without explanation, based on the outcome sought in that chapter."[13]

· "EPA's study selection is disturbing. First, there is evidence in the record supporting the accusation that EPA 'cherry picked' its data. Without criteria for pooling studies into a meta-analysis, the court cannot determine whether the exclusion of studies likely to disprove EPA's a priori hypothesis was coincidence or intentional. Second, EPA's excluding nearly half of the available studies directly conflicts with EPA's purported purpose for

Osteen's service as a tobacco lobbyist "might be something that an FDA lawyer would want to raise" in the lawsuit filed by cigarette makers to block the FDA's proposals to regulate tobacco advertising and impose restrictions on youth access to tobacco.[17] I took a much harsher view when talking to the same publication: "It seems like a little too sweet of a setup - having a case tried in North Carolina by a judge who used to be a lobbyist for tobacco farmers."[18]

In Judge Osteen's defense,

> ...[T]hose who have practiced law with Osteen, or who have argued before him during his 40-year legal career, paint a portrait of a man who is not easily swayed. Charges of a conflict of interest are 'balderdash,' says Kenneth W. McAllister, general counsel for Wachiva Corp., who in the mid-1980s prosecuted some of Osteen's clients as a U.S. Attorney.[19]

And Judge Osteen did uphold the FDA's jurisdiction over tobacco products in his April 25, 1997, decision in *Coyne Beahm v. FDA*, 966 F. Supp. 1376 (M.D.N.C. 1997). In *Coyne Beahm*, Judge Osteen

> ...ruled that the FDA may regulate cigarettes and smokeless tobacco products as drug delivery devices under the Federal Food, Drug and Cosmetic Act (FDCA). [Judge Osteen] upheld all FDA restrictions involving youth access and labeling. However, [he] 'stayed' or temporarily blocked implementation of most of these provisions. ...Finally, [Judge Osteen] invalidated the FDA's restrictions on advertising and promotion of cigarettes and smokeless tobacco.[20]

Nevertheless, some judicial ethicists would argue that Judge Osteen should have recused himself from the *Flue-Cured* case. According to Canon 2A of the Code of Conduct for United States Judges:

> A judge must avoid all impropriety and appearance of impropriety.... The test for appearance of impropriety is whether the conduct would create in reasonable minds...a perception that the judge's ability to carry out judicial responsibilities with...impartiality...is...impaired.[21]

Many would argue that Judge Osteen's presiding over a

> Primeamerica banned smoking in its subsidiaries "in response to" EPA's classification of ETS; (3) the California Restaurant Association has endorsed legislation to ban smoking in the workplace as a result of EPA's actions; (4) numerous states...have "proposed legislation to ban or restrict smoking in workplaces and other public areas"; and (5) legislation has been introduced to ban smoking in all federal buildings.[26]

The tobacco industry plaintiffs also complained that cigarette and tobacco sales had declined as a result of these actions, causing them to suffer economic losses.[27]

Even Judge Osteen admitted that the tobacco industry plaintiffs' claims might founder on the redressability prong. One line of authorities requires a concrete, particularized showing of redressability,[28] while the other requires that plaintiffs to demonstrate that there is a "substantial likelihood" that the requested relief will redress plaintiffs' injuries.[29] Judge Osteen found that the tobacco industry plaintiffs satisfied this prong, because they alleged that a permanent injunction requiring the EPA to withdraw its report and classification would prevent further economic and other injuries.[30] As Judge Osteen himself admitted, this "chain of causation is tenuous."[31] In addition, there existed scores of other studies that were prompting businesses and governments to ban or restrict smoking in public places. In light of these other studies, withdrawal of the EPA's report would probably not prompt many businesses and governments to rescind their restrictions.

In applying the court-developed test for standing - the zone of interest test - the Supreme Court has stated:

> In cases where plaintiff is not itself the subject of the contested regulatory action, the [zone of interest] test denies a right of review if the plaintiff's interests are so marginally related or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit.[32]

The zone of interest test can also be satisfied if the statute is intended to regulate plaintiff's actions.[33]

Judge Osteen found that the tobacco industry plaintiffs satisfied the zone of interest prong, because 1) the Radon Act requires the EPA Administrator to establish an advisory group comprised of industry representatives, among others, which Osteen characterized as "an indication that interests of the tobacco

> unreviewable agency action.
>
> Second, ...[a]lthough the Report and classification were not designated as a rule, the notice-and-comment procedure used by EPA otherwise follows that required for informal rulemaking. See 5 U.S.C. § 553. ...[A]lthough the final version of the Report was not itself published in the Federal Register or in the Code of Federal Regulations, it was released and the classification announced by the Administrator in a highly-publicized ceremony. The use of such procedures would suggest that EPA intended the Report and classification to have a regulatory effect, as Plaintiffs have alleged. (Complaint pp. 2, 81)
>
> Third, the Report and classification have in fact had a regulatory effect, albeit an indirect one.[40]

But one can easily counter that the EPA was merely acting according to the dictates of the Radon Act's mandate to 1) conduct research concerning the identification and characterization of sources of indoor air pollution and research relating to the health effects of that pollution on human health; and 2) disseminate this information to assure the public availability of the findings of such research. The EPA followed notice-and-comment procedure merely to disseminate its classification for public comment. The EPA issued no rule or regulation. Judge Osteen cites no authority for his proposition that indirect regulatory effects constitute agency action. He asserts instead that,

> Due to the prohibition of regulatory action contained in the Radon Act, any regulatory effect of an act carried out under the authority of the of the Radon Act must, of necessity, be indirect. Therefore the court does not find the indirect effect of the Report and classification to be fatal to the Complaint.[41]

But doesn't simple logic dictate that one conclude that agency action is impossible in this case as Congress has prohibited regulatory action under the Radon Act?

Judge Osteen also found that the EPA's 1992 report and classification constituted final agency action because

> First, the agency action is definitive. The Report itself concludes that ETS is in fact a known human carcinogen, not merely that ETS might be a carcinogen. Nor does the Report simply recommend

Osteen is really reaching when he discusses "indirect regulation" and "de facto regulation." This sort of reaching represents the worst of judicial activism.

In his most shocking departure from normal principles of administrative law, Judge Osteen chose to review the basic science - the epidemiology, statistical analysis and scientific judgment - behind the EPA's report, and substituted his "scientific" opinion for that of the EPA, its Science Advisory Board, the IAQC, the U.S. Department of Health and Human Services, the National Cancer Institute, the Surgeon General, and many major health organizations.[48] As Tim Filler of Prospect Associates put it,

> This is simply not the purview of the federal courts. Under normal principles of administrative law, Judge Osteen should not be reviewing the science behind the EPA report. His decision asks us to accept his interpretation of scientific evidence over the conclusions of the experts convened by EPA. Not surprisingly, Judge Osteen's conclusions on the science seem to have been informed solely by the tobacco companies' briefs.[49]

## Now, Wait Just a Cherry-Pickin' Minute!

Judge Osteen's accusing the EPA of "cherry picking" its data seems odd in light of the fact that the EPA seems to have good reasons for ignoring the data that it did. The EPA ignored 1) studies of childhood exposure to ETS on the theory that they relied upon distant memories and more limited lifetime exposure to ETS; and 2) studies of workplace exposure to ETS because of potential confounders. The exclusion of these types of studies seems to make good common and scientific sense,[50] but Judge Osteen found the EPA's arguments for doing so unpersuasive.[51]

Some of the studies excluded by the EPA were also arguably tainted by the influence of the tobacco industry. Judge H. Lee Sarokin, who presided over the *Haines v. Liggett Group, Inc.* case, once called the tobacco industry "the king of concealment and disinformation"[52] - a pithy remark that led an appellate court to disqualify him from further consideration of the case on the grounds of "an appearance of partiality."[53] Judge Sarokin's remark is more than borne out by the tobacco industry's research and strategy on ETS.

The issue of secondhand smoke has always greatly troubled the tobacco industry. In fact, internal tobacco industry documents

> Documents suggest that the industry was happy to oblige. In a 1993 summary of research activities by BAT Industries, the parent company of Brown & Williamson, a company official assessed BAT's strategic objectives as follows: "Conduct research to anticipate and refute claims about the health effects of passive smoking." Likewise, in a 1981 document from Philip Morris, an executive lamented the dearth of scientific information on which to support the company's public position. He suggested funding studies "with the intent to publish data which refutes specific assertions by the antismoking forces."[61]

Proof that the tobacco industry followed through on this strategy to great advantage can be found in a May 20, 1998 literature review published in *The Journal of the American Medical Association*. Of the more than 100 major studies in the past 13 years to have examined the health effects of passive smoking, 63 percent found evidence of harm, ranging from acute and chronic respiratory problems to cancer. Of the reports that were inconclusive or found no health effects, scientists funded by tobacco companies wrote nearly 75 percent. Among the studies written by people who had taken funding from tobacco industry sources, 94 percent found secondhand smoke harmless. Of the studies written by researchers without tobacco industry connections, 87 percent concluded that secondhand smoke was harmful. The evidence "suggests that the tobacco industry may be attempting to influence scientific opinion by flooding the scientific literature with large numbers of review articles supporting its position."[62]

Similar findings were made in a recent paper published in the July 1998 issue of the *American Journal of Public Health* on meta-analyses of workplace exposure to environmental tobacco smoke:[63]

> The major significance of Wells's paper...lies in its refutation of 5 other recent meta-analyses of the relationship between lung cancer and workplace environmental tobacco smoke. Wells meticulously elucidates how these other meta-analyses obscured the finding of any relationship because they failed to take account of errors in the underlying studies accepted into their database. When these errors are corrected and all 14 of the original investigations are used (regardless of the selection criteria adopted by Wells), the result is a combined relative risk of 1.19 (95% CI = 1.07, 1.34)....

> ...by challenging the scientist's work in newspaper advertisements. According to Stanton Glantz, the University of California at San Francisco professor who has helped make many of the tobacco papers public, the industry attacked Hirayama's study at the same time its own experts were privately agreeing with him. In a 1981 memo from the Tobacco Institute, a Brown & Williamson corporate lawyer writes: "[A tobacco industry scientist] replied with a strong statement that Hirayama was correct, that the TI knew it, and that the TI published its statement about Hirayama while knowing that the work was correct."[70]

According to *U.S. News & World Report*, a spokesman for Brown & Williamson said the company could not comment on these allegations about tobacco industry cherry picking and bullying.[71]

Yet at the same time the industry was dismissing what one cigarette company executive called "moronic, pop-scientific pronouncements,"

> ...the industry was acknowledging the risks of secondhand smoke by trying to devise a safer cigarette. The author of a BAT memo from 1983 said a research conference "should consider the reduction of specific biological activity [a euphemism for disease] in sidestream smoke."[72] Although health issues represented "constraints on the tobacco industry as whole," said the author of a 1982 memo from BAT, "...within them lies the opportunity for commercial exploitation."[73]

So, while the tobacco industry has publicly downplayed the hazards of secondhand smoke as an unproven "controversy," documents suggest that the industry has, for years, accumulated evidence that passive smoking is, in fact, dangerous. Clearly, the tobacco industry is, as Judge Sarokin alleged, the "king of concealment and disinformation." One might easily dub the tobacco industry the "king of the cherry pickers," and one wonders why Judge Osteen did not aim any of his harsh comments about the selective use of information at the industry.

## Who's Manipulating Whom?

Tobacco industry critics of the EPA's 1992 report have long accused the agency of statistical manipulation in order to come to a predetermined conclusion. Judge Osteen repeated this

in the non-cancer respiratory effects portion of the 1992 report only because "there was less prior evidence from smokers to suggest that secondhand smoke would cause bronchitis, pneumonia, and ear infections in children."[77]

In its June 1994 response to tobacco industry criticisms, the EPA also noted "the remarkable consistency of results across studies that support a causal association between secondhand smoke and lung cancer" in the 30 epidemiology studies. In fact, the EPA noted in its 1994 report, "It is unprecedented for such a consistency of results to be seen in epidemiology studies of cancer from environmental levels of a pollutant."[78]

When the measure being examined is that of whether the husband ever smoked, 24 of the 30 studies show an increase in risk for the nonsmoking wives. Due to the small sample size of many of the studies, only nine of them showed statistically significant increases. As the EPA points out, however, "...the probability that this many of the studies would be statistically significant merely by chance is less than *1 in 10 thousand*." (Emphasis in original)[79]

This simple measure of exposure minimizes true increases in risks because 1) many women categorized as never exposed to secondhand smoke were exposed to other-than-spousal sources of secondhand smoke; and 2) some women categorized as exposed "actually received little exposure from their husband's smoking. One can correct for this minimization of the results by examining the 17 studies that looked at cancer effects based on the subjects' level of exposure to secondhand smoke. In all 17 studies, an increased risk of lung cancer was found among the subjects who were most exposed. Nine of these studies were statistically significant, and the EPA reported that the probability that 9 out of 17 studies would be statistically significant merely "by chance is less than *1 in ten million*." (Emphasis in original)[80]

Finally all 14 studies which examined the relationship between level of exposure to secondhand smoke and cancer effects reported increasing cancer effects with increasing exposure. Ten of the studies reported statistically significant increases, and the EPA noted that "[t]he probability of this happening by chance is less than *1 in a billion*." (Emphasis in original)[81]

Two more recent papers used 95 percent confidence intervals and still found a statistically significant relationship between secondhand smoke and lung cancer. The first was the California EPA's 1997 report,[82] and the second was the review of workplace meta-analyses conducted by A. Judson Wells for the *American*

Tobacco industry critics claim that recent studies do not support the EPA's conclusions. This is not true. All four of the new lung cancer epidemiology studies - including 3 large-scale studies done in the United States - conducted since the literature review cutoff date for the 1992 EPA report support the conclusions contained in the 1992 report. Three large U.S. population-based case-control studies have been published since 1991 that confirm and extend the results of the pooled U.S. studies presented in the U.S. EPA report.[88]

The results of the 1994 Fontham study of women in two California and three Southern cities -- the largest case-control study on the subject ever conducted -- provides further vindication of the EPA's 1992 conclusions.[89] According to this study, published in the June 8, 1994 edition of the *Journal of the American Medical Association*, women who do not smoke and who have never smoked face a significant risk of developing lung cancer from exposure to environmental tobacco smoke. The study, funded by the National Cancer Institute, examined 653 women with lung cancer, age 65 and older, who never smoked and 1,253 healthy non-smoking women randomly selected from Health Care Financing Administration files on women in the same age group. The women studied resided in Atlanta, Houston, Los Angeles, New Orleans and the San Francisco Bay area.[90]

According to the study, women face a 30 percent greater risk of developing lung cancer if their husbands smoke in the home, a 39 percent greater risk of lung cancer if they are exposed to secondhand smoke in the workplace, and a 50 percent greater chance of lung cancer if they are exposed to environmental tobacco smoke in social settings. These increased risk figures are averages. The risk for the individual women studied increased with the amount of exposure to tobacco smoke. The researchers found, for example, that a nonsmoking woman's risk of developing lung cancer after being exposed to environmental tobacco smoke regularly as an adult doubled if that woman had been exposed to secondhand smoke as a child. At the level of highest exposure, women whose husbands smoked two packs a day for 40 years faced an 80% increased risk of developing lung cancer.[91]

According to Thomas Sellers, a University of Minnesota expert on smoking and lung cancer, this latest study's research results support the idea that the lung cancers occurring in smokers and nonsmokers are the same disease. Some scientists have speculated that the lung cancers occurring in smokers and nonsmokers are two different diseases.[92]

cases annually in infants and young children up to 18 months of age are attributable to environmental tobacco smoke, resulting in 7,500 to 15,000 hospitalizations.

· Exposure to secondhand smoke is associated with increased prevalence of fluid in the middle ear, symptoms of upper respiratory tract infection and a small but significant reduction in lung function.

· Environmental tobacco smoke exposure has been linked to an increase in both prevalence and severity of childhood asthma.[96]

These effects of secondhand smoke on children are more than enough reason for any citizen or government official to conclude that secondhand smoke needs to be regulated in order to prevent the public from being endangered by exposure to it.

## The Effect of Judge Osteen's Ruling on the Validity of State and Local Clean Indoor Air Measures?: Nada!

As Cliff Douglas, president of Tobacco Control Law and Policy Consulting in Ann Arbor, Michigan, recently pointed out, the tobacco industry "will use [Osteen's] decision fraudulently to mount an all-out assault against public and workplace smoking restrictions."[97] Indeed, in a statement, Philip Morris said the ruling "supports our view that...the enactment of severe smoking restrictions is not justified."[98] Charles A. Blixt, executive vice president and general counsel of R. J. Reynolds Tobacco Company said, "We feel vindicated by the federal court's decision that the EPA wrongly classified secondhand smoke as a cause of cancer in non-smokers. This decision should prevent the EPA from becoming a participant in the anti-smoking industry's crusade to ban smoking. The court's ruling supports Reynolds Tobacco's belief that science does not justify public smoking bans."[99] And newspapers as prominent as *The Washington Post* erroneously reported that Judge Osteen's decision "could imperil hundreds of local and regional ordinances banning indoor smoking."[100]

The tobacco industry will also use Osteen's decision to argue that plaintiffs in secondhand smoke cases cannot prove causation. Indeed, Michael York, a lawyer for cigarette maker Philip Morris Companies said the ruling could become an obstacle to people who try to sue tobacco companies for lung cancer, heart disease or other ailments that they claim were caused by secondhand smoke. "They have to prove that their injuries were in fact caused by secondhand smoke," said Mr. York, "and the EPA study has been a cornerstone of lawsuits."[101] I guess Mr. York thinks that

risk assessment on ETS in January 1993. Since then, another 239 localities have amended or enacted clean indoor air ordinances. Given the wealth of other scientific authority available to support the need for clean indoor air measures, it appears there is no going back, no matter what Judge Osteen says about the EPA's 1992 report.

Nor is the decision apt to cause employers and building operators throughout the country - who have banned smoking on nuisance as well as health grounds - to seriously reconsider their policies:

> The public reached its own conclusions about secondhand smoke years ago. Average citizens didn't need research to tell them that breathing other people's smoke made their eyes sting, their throats scratch, their lungs ache, their heads throb and their clothes smell. Science clearly corroborates what the public knows intuitively: Secondhand smoke is dangerous to one's health. Using single studies or court rulings to argue the point does not change this fact.[106]

Matthew Myers, executive vice president and general counsel for the National Center for Tobacco-Free Kids, an advocacy group in Washington, said he did not believe that the industry would use the ruling to challenge secondhand smoke laws already in place. And a cigarette industry official, speaking on the condition of anonymity, agreed. But one regulator, speaking on the condition of anonymity, said tobacco companies might seek to repeal laws in communities where support for antismoking measures was not overwhelming.[107]

"This country has fundamentally become a nation of . . . people who believe it is inappropriate to have to be in a place where they have to breathe tobacco smoke," Myers also said. "While the move to restrict smoking indoors could be temporarily set back by this decision," he said, "it won't be stopped."[108]

On balance, although Judge Osteen's ruling appears to be helpful to the industry, "I wouldn't," as Martin Feldman, an analyst with Salomon Smith Barney in New York, said, "overstate...the benefit."[109] At most, as antitobacco activist Scott Ballin recently pointed out: "This is a public-relations blip."[110]

My colleague, Robert Kline, a part-time staff attorney at the Tobacco Control Resource Center and director of the Tobacco Control Legal Clinic at Northeastern University law school, contended the ruling would not affect the ongoing tobacco wars because other studies have confirmed the EPA findings. Asked

6 Paul Raeburn, *Secondhand Smoke. It's Deadly. Period.*, BUSINESS WEEK, August 3, 1998.

7 *See, e.g., Louisiana Public Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986).

8 42 U.S.C. § 7401 (1994). The Radon Research Act was enacted by Congress as Title IV of the Superfund Amendments and Reauthorization Act of 1986 (SARA) and codified with the Clean Air Act at 42 U.S.C. § 7401. The Act was based on Congress' finding: "exposure to naturally occurring radon and indoor air pollutants poses public health risk[s]," *id.* at § 7402(2); "Federal radon and indoor air pollutant research programs are fragmented and underfunded," *id.* at § 7402(3); and an "information base concerning exposure to radon and indoor air pollutants should be developed . . . ." *Id.* at § 402(4).

9 *Id.* at § 7403(c).

10 *Flue-Cured*, *supra*, note 1.

11 *Id.*

12 *Id.*

13 *Id.*

14 *Id.*

15 *Id.*

16 Associated Press, *Judge's Past Work as a Tobacco Lobbyist Questioned*, ASHEVILLE CITIZEN-TIMES, August 20, 1995.

17 Justin Catanoso, *Tobacco Country's Homegrown Judge*, BUSINESS WEEK, September 9, 1996.

18 *Id.*

19 *Id.*

20 Raymond C. Porfiri, *Federal Court Upholds FDA Youth Access and Labeling Restrictions But Strikes Down Advertising and Promotion Regulations*, TOBACCO CONTROL UPDATE, Vol. 1, Issues 3 & 4 (Summer/Fall 1997) at 37.

21 28 U.S.C. § 372 (1998).

232, 239-40 (1980).

44 *Flue-Cured*, supra, note 36 at 1143.

45 *Id.*

46 *Flue-Cured*, *supra*, note 1.

47 *Id.*

48 All of these organizations had reviewed and endorsed the EPA's 1992 report. *See*, U.S. Environmental Protection Agency, SETTING THE RECORD STRAIGHT: SECONDHAND SMOKE IS A PREVENTABLE HEALTH RISK (1994).

49 Memorandum from Tim Filler, Prospect Associates, to the ASSIST Media Network, *Talking Points for EPA Ruling* (July 21, 1998).

50 *See, e.g.*, Deborah E. Barnes and Lisa Bero, *Why Review Articles on the Health Effects of Passive Smoking Reach Different Conclusions*, JAMA, Vol. 279, No. 19 (May 20, 1998) at 1566; A. Judson Wells, *Lung Cancer from Passive Smoking at Work*, AMERICAN JOURNAL OF PUBLIC HEALTH, Vol. 88, No. 7 (July 1998); Lester Breslow and Robert Elashoff, *Editorial: Significance of Workplace Smoking*, AMERICAN JOURNAL OF PUBLIC HEALTH, Vol. 88, No. 7 (July 1998) at 1101.

51 *Id.*

52 *Haines v. Liggett Group, Inc.*, 140 F.R.D. at 683 (D.N.J. 1992).

53 *Haines v. Liggett Group, Inc.*, 975 F.2d 81 (3rd Cir. 1992).

54 Susan Headden et al., *Secondhand Smokescreen*, U.S. NEWS & WORLD REPORT, August 3, 1998.

55 Graham E. Kelder, Jr. and Richard A. Daynard, *The Role of Litigation in the Effective Control of the Sale and Use of Tobacco*, 8:1 STANFORD LAW & POLICY REV. 63 (1997).

56 15 USC §§ 1331-1341 (1994).

57 Richard A. Daynard, *The Third Wave of Tobacco Products Liability Cases*, 30 TRIAL 34 (1994).

58 Kelder and Daynard, *supra*, note 55.

77 *Id.*

78 *Id.*

79 *Id.*

80 *Id.*

81 *Id.*

82 California Environmental Protection Agency, HEALTH EFFECTS OF EXPOSURE TO ENVIRONMENTAL TOBACCO SMOKE (1997).

83 A. Judson Wells, *supra*, note 63.

84 National Research Council, ENVIRONMENTAL TOBACCO SMOKE: MEASURING EXPOSURES AND ASSESSING HEALTH EFFECTS (1986).

85 U.S. Department of Health and Human Services, REPORT OF THE SURGEON GENERAL: THE HEALTH CONSEQUENCES OF INVOLUNTARY SMOKING (1986).

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